

**Remarks**

*Examined Claims*

Applicants acknowledge that claims 2, 11-16, 18, and 27-36 are withdrawn as being drawn to a non-elected invention or as not being encompassed by the elected bola compound. In addition, further to the Applicants' election of species of the compound of Formula 1 as depicted in Figure 1, claims 3, 4, 19, and 20 should also be withdrawn because the bola amphiphile has a hydrophilic head group in which one is peptidic and one is non-peptidic. Applicants have marked claims 3, 4, 19 and 20 accordingly. Claims 1, 5-10, 17, and 21-26 are examined. Claims 7-10 and 23-25 are objected to as being dependent on rejected claims.

*Objections*

Claim 4 was objected for grammatical reasons. Applicants have amended claim 4 to include the hyphen between "bond" and "forming".

*35 USC 112, Second Paragraph Rejection*

Claims 1, 3-6, 17, and 19-21 are rejected under 35 USC 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The language "composition" is rejected as claims 1 and 17 do not recite a second compound or material. Applicants respectfully disagree. The language "composition" is an accepted claim term that would provide for the existence of additional components in addition to the bola amphiphile. Applicants contend that there is nothing ambiguous about the language "composition" and respectfully request withdrawal of the rejection thereof.

The language "the one or more" in claim 25 is rejected because it lacks antecedent basis. Applicants have amended claim 25 to recite "at least one bola amphiphile," which has antecedent basis in independent claim 22.

*Prior Art Rejections*

Claim 1, 5, 17, 19, and 21 are rejected under 35 USC 102(b) as allegedly being anticipated by Kogiso (*Biochimica et Biophysica Acta, General Subjects* 1475(3), 346-352, 2000). It is stated that Kogiso discloses the invention substantially as claimed. Applicants respectfully traverse the rejection.

Kogiso describes the self-assembly of peptide fibers from valylvaline bola-amphiphiles. Specifically, the molecules employed in Kogiso have the general formula: L-valyl-L-valyl-(CH<sub>2</sub>)<sub>n</sub>-L-valyl-L-valyl. The valylvaline end groups allegedly constitute the lyophobic portion of the molecule and the CH<sub>2</sub> moieties constitute the lyophilic portion. Accordingly, the amphiphiles of Kogiso have two lyophobic portions connected to a single lyophilic portion. The elected claims, on the other hand, are directed to a bola amphiphile composition comprising a lyophobic moiety coupled at one end to a first lyophilic head group and coupled at a second end to a second lyophilic head group. Clearly, nothing in Kogiso describes the claimed invention. Nevertheless, in order to better clarify the invention, Applicants have amended the claims to direct it more towards the elected species in which one lyophilic head group is non-peptidic and the other lyophilic head group is peptidic. Kogiso, on the other hand, has two lyophilic portions that are identical. Therefore, Kogiso does not meet each and every element of the claims. Withdrawal of the rejection is respectfully requested.

Claims 1, 5, 7, and 21 are rejected under 35 USC 103 as allegedly being unpatentable over Knudsen (USP 6,458,924). The Office Action states that Knudsen discloses various analogs of GLP-1 in which one of the internal lysine groups is acylated with a hydrophobic group. The Action concludes that while the term “bola” is not used to describe the peptides, the disclosed peptides meet the description of claim 1. Applicants respectfully traverse the rejection.

Applicants respectfully submit that the ‘924 patent does not teach or suggest a bola amphiphile composition comprising a lyophobic moiety having a first end and a second end, wherein the first end of the lyophobic moiety is chemically coupled to a first lyophilic head group, and the second end of the lyophobic moiety is chemically coupled to a second lyophilic head group, where at least one lyophilic head group is non-peptidic

and the other lyophilic head group is peptidic. While the '924 GLP-1 analogs described appear to have a lyophobic moiety, it does not have at one end, a non-peptidic lyophilic group, and, at the other end, a peptide lyophilic group. The Action appears to suggest that the carboxyl group and amino group of the '924 analog constitute the lyophilic head groups to satisfy the claims. However, Applicants have clarified via these amendments that one lyophilic head group is not peptidic and the other is peptidic. The carboxyl and amino groups do not read on the peptidic and non-peptidic lyophilic head groups defined in the claims. Therefore, the '924 patent does not teach or suggest every element of the claims. Withdrawal of the rejection is respectfully requested.

Claims 1, 6-10, 22 and 26 are rejected under 35 USC 103 as allegedly being unpatentable over Darcy (US 2003/0092672). The Action states that Darcy discloses bola amphiphiles, which form micelles. The Action concludes that the claims are rendered obvious. Applicants respectfully traverse the rejection.

Darcy describes the preparation of soluble amphiphilic derivatives in which a hydrophobic macrocyclic group has attached on each unit forming the macrocycle, two or more hydrophilic groups, and on the opposite side of each unit forming the macrocycle, one or more lyophilic groups. The resulting molecule is allegedly amphiphilic in character.

Applicants respectfully contend there really is no "first end" or "second end" of the lyophobic portion because that component is cyclic. There are no "ends" to the cyclic portion of the molecule. The bola amphiphile compositions of the present claims, on the other hand, have a lyophobic moiety having a first end and a second end, wherein the first end of the lyophobic moiety is chemically coupled to a first lyophilic head group, and the second end of the lyophobic moiety is chemically coupled to a second lyophilic head group, where at least one lyophilic head group is non-peptidic and the other lyophilic head group is peptidic. Darcy does not teach or suggest each and every element of the claimed invention. Withdrawal of the rejection is respectfully requested.

**Response to Office Action**

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*Conclusion*

Applicants respectfully submit that the claims are allowable. In the event the Examiner believes a conference would expedite prosecution, he is courteously invited to contact the undersigned.

Respectfully submitted,

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